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Biotechnology

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Report Highlights:
Since 1998, the EU has approved three biotech events in the face of considerable member state (MS) resistance. About 30 events are in the pipeline still waiting approval. Currently, marketing bans on EU-approved biotech events are in effect in 6 MSs. On April 18, 2005 the Commission introduced emergency inspection measures to identify the presence of Bt10 corn in U.S. exports of corn gluten feed and brewers grains to the EU. The debate on agricultural biotechnology in the EU is highly politicized. Many of the contentious issues now confronting the EU are not related to human health and environmental safety. Over the last 6 years the EU has implemented a comprehensive regulatory system to guarantee that biotech products are fully evaluated to ensure their safety. The EU and MSs remain deadlocked on the search for seed labeling legislation to cover the adventitious presence of biotech seed and coexistence measures for biotech, conventional, and organic agriculture.

Includes PSD Changes: No
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Executive Summary

Since 1998, the EU has approved three biotech events. About 30 events are in the pipeline waiting approval. Currently, marketing bans on EU-approved biotech events are in effect in 6 member states. The Commission with the scientific backing of the European Food Safety Authority (EFSA) will ask the June Environmental Council to lift the bans.

On April 18, 2004, the Commission introduced emergency inspection measures to identify the presence of Bt10 corn in U.S. exports of corn gluten feed and brewers grains to the EU. The system will remain in place for 6 months at which time a review will be conducted to determine whether it is still necessary.

The debate concerning biotechnology in the EU is highly politicized. Many of the contentious biotech issues now confronting the EU are not related to human health and environmental safety. Over the last 6 years the EU has implemented a comprehensive regulatory system to ensure that biotech products are fully evaluated to ensure their safety.

The EU and the member states are now deadlocked over a number of issues that are based on economic considerations, and not safety: 1) the on-going search for seed labeling legislation for biotech events approved by EFSA and 2) the development of coexistence measures for biotech, conventional and organic agriculture that equally protect the interests of all farmers; and 3) the lifting of the marketing bans in 6 member states.

Biotechnology Trade and Production

Status of Product Approvals

Syngenta's Bt11 sweet corn for human consumption was authorized for marketing in May 2004. Monsanto's NK603 herbicide tolerant corn was authorized in November 2004 for import for both food and feed uses. These are the only biotech products that the EU has authorized for marketing since 1998.

Currently, there are about 30 biotech events in the pipeline for approval. Those furthest along in the process are presented in the following table.

Event	Company	Use	Risk Assessment	Status
Herbicide Tolerant Rapeseed GT73	Monsanto	Import/Processing/feed	Positive	At Commission for Final Consent
Insect Resistant Corn MON863	Monsanto	Import/Processing/feed and food	Positive	At Council for feed. Commission to refer to Council for food.
Herbicide Tolerant Corn GA21	Monsanto	Food	Positive	Commission to Refer to Council
Insect Resistant Corn MON863XMON810	Monsanto	Import/Processing/feed and food	Pending	EFSA opinions (2) pending
Insect Resistant & Herbicide Tolerant YieldGard/Roundup Ready Corn	Monsanto	Import/Processing/feed and food	Pending	Rapporteur Review (Spain) and EFSA opinion pending
Insect Resistant Corn1507	Pioneer/ Mycogen	Import/Processing/Food/Feed/ Cultivation	Positive	Reg. Cmt. Decision, Sept for cultivation, Commission to refer to Council for food.
Insect Resistant Bt11 Corn	Syngenta	Cultivation	Positive	N/A
Herbicide Tolerant Hybrid Rapeseed (Ms8Rf3)	Bayer Crop Science	Import/Processing/Feed	SCP 1998 positive 1/	EFSA opinion pending
Herbicide Tolerant Rapeseed (T45)	Bayer Crop Science	Import/Processing	To be sent to EFSA	Application in UK since March 2004
Herbicide Tolerant Rice Liberty Link 62	Bayer Crop Science	Import/Processing/Food/Feed	EFSA opinions pending	N/A
Herbicide Tolerant Cotton Liberty Link 25	Bayer Crop Science	Import/Processing/Feed/Food	To be sent to EFSA	Applications in Spain, 3/2004 and NL, 3/2005

1/ Positive risk assessments issued under the old Scientific Committee on Plants (SCP) under Directive 90/220.

No EU regulatory committee made up of the member states has voted in favor of authorizing the marketing of a product despite consistently positive risk assessments from EFSA.

For both BT 11 and NK 603, the Commission recommended that the member states authorize the marketing of these products based on the positive risk assessments issued. Despite this the member states failed to reach a qualified majority for or against approval, and the Commission then asked the Council of Ministers to come to a decision. After 3 months, the Council also deferred and sent the matter back to the Commission. The Commission then authorized the marketing of the two biotech events.

The Council of Minister's involvement in the approval process for biotech events is a dramatic departure from normal legislative procedures. Agriculture Ministers meet to approve major CAP reforms or EU trade policy positions in the WTO Doha round. Typically, working level officials drawn from the member states consulting in a regulatory committee would make decisions on biotech events.

Biotechnology Policy

Regulatory Framework

Technology providers can file an application for the authorization of agricultural biotech products under two EU regulations. Under Regulation (EC) No 1829/2003, a company can file a single application for the biotech event and all its uses (known as the "one door, one key principle"). The company submits the application to the competent authorities of the member state where the product will first be marketed. Within 14 days, the member state must forward the application to the European Food Safety Authority (EFSA) for review.

EFSA conducts a single risk assessment and a single authorization can be granted for an event and all its uses (cultivation, importation, processing into food/feed or industrial products). While EFSA attempts to issue an opinion within 6 months, they may request additional information from the applicant thus lengthening the time frame. If EFSA issues a positive risk assessment, the application is forwarded to the European Commission, who has responsibility for risk management.

The Commission will then present a proposal recommending that the member states authorize the product. The Commission may impose certain conditions (e.g., harvesting, transport, and monitoring) concerning the product. The Commission has 3 months to draft the proposal. The member states then review and vote on the proposal in a regulatory committee. A qualified majority (QM) is required to approve or defeat the proposal. If the proposal fails to obtain a QM, the proposal then goes to the Council of Ministers for review. The Council has three months to make a decision. If the Council fails to reach a decision, the Commission may then authorize the marketing of the product.

A company can also file an application under Directive 2001/18/EC for the purpose of marketing a biotech event for cultivation, importation and processing into different products. While the procedure under this directive resembles that of Regulation (EC) No 1829/2003, there are some differences. When the application is submitted in the member state, that county's competent authorities perform an assessment. Should they issue a negative assessment, the applicant's only option is to submit the file in another member state. However, if the member state does issue a favorable assessment, then the results are shared with the Commission and all other member states may approve the event for marketing within the EU or raise objections. Should objections be raised, then the Commission will ask

EFSA to conduct a study. From this point on, the approval procedure resembles that of Regulation (EC) No 1829/2003.

The Commission's Directorate General for Health and Consumer Protection--known by the French acronym SANCO--handles applications that are submitted under Regulation (EC) No 1829/2003. Typically, the Agriculture Council of Ministers reviews Commission proposals under this legislative authority when the member states are deadlocked. The Directorate General for the Environment handles applications submitted under Directive 2001/18/EC with the Environment Council of Ministers reviewing Commission proposals when the member states fail to reach a QM.

Political Factors

The debate concerning biotechnology in the EU is highly politicized. Many of the contentious biotech issues now confronting the EU are not related to human health and environmental safety. Over the last 6 years the EU has implemented a comprehensive regulatory system to ensure that biotech products are fully evaluated to ensure their safety. The European Food Safety Authority (EFSA) and the member state competent authorities have the final say before a product is authorized for release on the market.

Now the EU and the member states are deadlocked over a number of issues that are based on economic considerations, and not safety: 1) the on-going search for seed labeling legislation for biotech events approved by EFSA and 2) the development of coexistence measures for biotech, conventional and organic agriculture that equally protect the interests of all farmers. Similarly, the EU Commission has stated that the marketing bans in 6 member states are not based on legitimate safety concerns.

Product Authorizations

Please refer to the link below for a list of biotech food products that were approved under the Novel Food Regulation (EC) No 258/97:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/258-97-ec_authorised_en.pdf

The Novel Food Regulation (EC) No 258/97 has since been superseded by Regulation (EC) 1829/2003.

Please refer to the link below for a list of biotech feed products that were approved under the Directive No 2001/18/EC:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/2001-18-ec_authorised_en.pdf

On April 18 2005, the Commission published a list of 26 biotech products that have been legally on the EU market since before the new legislative framework was introduced in April 2004 for authorizing biotech food and feed had entered into effect. These so-called "existing products" were either approved under former EU legislation, or did not require approval at the time that they were put on the market. They have been added to a specific section of the Community register of biotech food and feed in order to clarify exactly which products are permitted to be sold in the EU.

Since the entry into force of Regulation 1829/2003 on biotech food and feed in April 2004, all biotech products seeking to enter the EU market as food or feed have to undergo a thorough authorization procedure, including a scientific safety assessment by EFSA. However, there are certain biotech food and feed products that can be legally sold in the EU according to the rules in place before Regulation 1829/2003.

In order to cover these GM products, Regulation 1829/2003 stipulated that operators who wished to continue marketing an "existing product" had to notify the Commission and submit detailed information on the biotech event before October 18, 2004. Non-notified products will no longer be allowed on the EU market. The Commission, in co-operation with the Joint Research Center, examined the validity of the notifications it received and agreed to enter 26 biotech products into a specifically created section of the Community register of genetically modified food and feed. Once one of these "existing products" is on this register, it can legally be sold in the EU for a set period of between 3-9 years, after which it has to resubmit an application for the renewal of the authorization.
For the register of biotech "existing products", see:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/register_notification/index.htm

Specific legislation governing these products can be found at the following link:

http://europa.eu.int/comm/food/food/biotechnology/gmfood/reg641_2004_en.pdf

Member State Marketing Bans of Biotech Products

Marketing bans for a number of events remain in effect in effect in Austria, Denmark, France, Luxembourg, Germany, and Greece. In November 2004, EU member states met in a regulatory committee to review the Commission's proposal recommending the lifting of the bans. The Commission based its recommendation on EFSA opinions asserting that there was no scientific basis for the member state bans. Nevertheless, the regulatory committee failed to reach a decision and the Commission has referred the matter to the Council who has three months to make a decision. (It is expected that the June Environment Council will consider the proposal.) Since it is likely the Council will fail to reach a decision, the Commission will then be able to lift the bans.

The events banned are presented in the following table. The Commission had approved these products for marketing based on positive risk assessments issued by EU scientific committees.

Country	Event Banned	Date of Ban
Austria	Syngenta Bt176 Corn, Bayer T25 Corn, Monsanto MON810 corn	1997, 2000, 1999
France	Bayer Rapeseeds Topas 19/2 and MS1XRf1	1998 for both
Germany	Syngenta Bt176 corn	2000
Greece	Bayer Rapeseed Topas 19/2	1998
Luxembourg	Syngenta Bt176	1997

Coexistence

Agriculture Commissioner Fischer-Boel has indicated that she is giving consideration to modifying the current Commission policy that encourages countries to develop their own guidelines for the coexistence of biotech and conventional agriculture. She has recently suggested the possibility of developing a EU "framework legislation" that would presumably impose tighter controls on farmers, and yet still allow some flexibility to account for differences among countries. This would mark a departure from the non-binding guidelines (http://europa.eu.int/comm/agriculture/res/index_en.htm) published by the Commission in July 2003. However before proposing any changes, Commissioner Fischer-Boel will await the results of a EU review of the experiences of the member states in developing coexistence laws due out in late 2005.

Austria, Denmark, and Italy have taken the lead in pressing the Commission to adopt a EU-wide regulation for the coexistence of biotech crops and conventional and organic agriculture. Along with Germany, each of these countries has drafted coexistence laws that are extremely restrictive in terms of what farmers of biotech crops are required to do. Faced with such challenges, farmers will likely not run the risk of planting biotech crops. Moreover, certain aspects of these laws would appear to violate the internal market rules of the EU which guarantees "free circulation", and is reiterated in Article 22 of Directive 2001/18/EC which regulates the deliberate release into the environment of genetically modified organisms. In the past, the Prodi Commission has been critical of Germany's proposed coexistence law.

Labeling

Labeling regulations for products containing or consisting of GMOs are presented in Regulation (EC) No 1830/2003, article 4B. In general, these labeling regulations apply to bulk agricultural commodities such as whole grains and oilseeds. The scope of GMO products covered is defined in Directive 2001/18.

Labeling regulations for food and feed products that are produced from GMOs are presented in Regulation (EC) No 1829/2003, articles 12-13 for food and articles 24-25 for feed. These products have undergone varying degrees of processing.

In general, all food and feed products containing/consisting of GMOs and/or produced from GMOs, including products that no longer contain detectable traces of GMOs must be labeled. The allowable adventitious presence level for EU-approved varieties of GMOs for use in food and feed is set at 0.9 percent. Above this level, all products must be labeled. For GM varieties, which are not yet formally approved but which have received a positive EU risk assessment, the adventitious presence level is set 0.5 percent. This provision will expire after 3 years. Above this threshold, the product is not allowed on the EU market. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable.

The regulation does not require labeling of products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

An Example of to How to Label for Food Produced from GMOs

Article 13 of Regulation 1829/2003 specifies the wording to be used on the label as follows:

(a) Where the food consists of more than one ingredient, the following wording must follow immediately after the ingredient concerned, in brackets: "genetically modified" or "produced from genetically modified [name of ingredient]. A compound ingredient with a constituent X which is produced from a GMO Y must be labeled "contains X produced from genetically modified Y.

Example: a biscuit containing soy flour derived from GM-soy must be labeled "contains soy flour from genetically modified soy".

(b) Where the ingredient is designated by the name of a category, the following wording must be used in the list of ingredients: "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]".

Example: for vegetable oils containing rape oil produced from genetically modified rape, the reference "contains rape oil from genetically modified rape" must appear in the list of ingredients.

(c) Where there is no list of ingredients, the words "genetically modified" or "produced from genetically modified [name of organism]" must appear clearly in the labeling.

Example 1: "a spirit containing caramel produced from genetically modified corn".
Example 2: "genetically modified sweet corn"

(d) If the product consists of or contains a GMO e.g. sweet corn in a Mexican salad, the label must state "genetically modified sweet corn"

The designations in (a) and (b) may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.

Labeling for Genetically Modified Microorganisms (GMMs) and “Processing Aides”

The Commission stated on September 24, 2004 that “food and feed (including food and feed ingredients such as additives, flavorings and vitamins) produced by fermentation using a GMM which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No. 1829/2003. These food and feed have to be considered as having been produced with the GMM, rather than from the GMM.”

Therefore, these products don’t have to be labeled like products produced from agricultural biotechnology. This was contrary to the original position taken by the Commission in April 2004 when the Commission had proposed that these products be labeled (see point 2D, Fermentation Products).

Likewise in the case of GMMs such as yeast used in alcoholic beverages, the Commission doesn’t require labeling if the GMM is not present in the final food. Like vitamins, the EU justifies its stance on the basis that the “…resulting food is considered to have been produced with a GMM, but not from a GMM”. This is also true of cheese that has been produced “with” the use of chymosin, an enzyme that is genetically modified. Such processing aides don’t fall within the scope of the labeling regulations.

Status of Seed Labeling Legislation

While the former Prodi College of Commissioners had intended in September 2004 to propose a seed labeling amendment for the presence of GM seeds commingled with conventional seed, the different directorate generals (DG) couldn’t reach agreement. Reportedly, DG Environment and DG Agriculture pressed for a maximum AP of 0.3 percent for corn whereas DG Health and Consumer Protection favored 0.5 percent. There was agreement of 0.3 percent for rapeseed. Faced with this impasse, the Prodi Commission called for additional research to determine the economic impact of different thresholds on farmers and seed producers before taking any further action. The Commission has been

trying to develop a policy on seed labeling since 2001 when the Scientific Committee on Plants presented recommendations on AP levels for a number of biotech seeds (corn—0.5 percent; soybeans—0.7 per cent; and rapeseed –0.3 percent).

In the absence of a EU seed labeling regulation for the presence of biotech seed, the Commission has stated "that since no thresholds for the AP of GMOs in conventional seed lots have been established, any seed lot containing GM seed authorized for the cultivation has to be labeled as containing GMOs. Seed lots containing GM seeds that not authorized for cultivation, can not be marketed in the EU."

Some members of the new Barroso Commission appear to favor setting AP thresholds at the level of detection--0.1 percent. In his parliamentary hearings in September, Environment Commissioner Stavros Dimas voiced support for 0.1. Likewise, Agriculture Commissioner Mariann Fischer-Boel, one of the architects of Denmark's tough coexistence law and a strong proponent of organic agriculture, also reportedly favors very low thresholds.

Traceability

Under the rules for traceability in Regulation (EC) No 1830/2003, business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of the placing on the market. Information concerning the presence of GMOs must be transmitted throughout the commercial chain and must be retained for five years. The regulation covers all products, including food and feed, containing or derived from GMOs that received an EU authorization, e.g. GM seeds, GM grain, tomato paste and ketchup derived from a GM tomato or starch, oil or flour produced from a GM maize.

--for GMOs intended for deliberate release into the environment: operators must transmit specified information on the identity of the individual GMO(s) a product contains;

--for GMOs intended for food, feed or for processing: business operators may either transmit the specified information or transmit a declaration that the product shall only be used as food or feed or for processing together with the identity of the GMO(s) from which the product was derived;

--for food and feed produced from GMOs: operators must inform the next operator in the chain that the product is produced from GMO(s).

On January 14, 2004, the European Commission published Commission Regulation 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs. A unique identifier is assigned to each GMO as a means of indicating its presence and reflecting the specific transformation event covered by the consent or authorization for placing that GMO on the market.

Cartagena Biosafety Protocol

The EU is a signatory to the biosafety protocol. To align its regulatory framework with the provisions of the Protocol, the EU has implemented a Regulation on transboundary movements of GMOs that addresses in particular exports of living modified organisms. The Regulation was approved by the Council of Ministers on 13 June and entered into force in September 2003.

Trade Barriers

The current EU regulatory system and approval process for biotech products is a barrier to trade. Since 1998, the EU has approved only 3 biotech events. Currently, the EU has a backlog of 30 products that are awaiting approval. In view of the unwieldy and less than transparent process for application and approval, we do not expect this backlog to be reduced significantly in the short term.

In May 2003, the United States announced that it would initiate a WTO dispute settlement process focused on the EU's de facto moratorium on approvals of biotechnology products, and on the existence of individual Member State marketing prohibitions on previously approved biotechnology products. In March 2004, the WTO formed a panel to consider the challenge of the United States, Argentina and Canada to the EU's moratorium on the approval of new agricultural biotech products. The final panel report is expected in the summer of 2005.

On April 18, 2004, the EU's newest regulations (EC No 1829/2003 and EC No 1830/2003) concerning the labeling and traceability of biotech food and feed products went into effect. These new regulations were intended to address the Member States' concerns about protecting consumer and environmental interests. Despite the passage of these regulations, the Member States continue to thwart the approval of new biotech products that have received favorable risk assessments from the European Food Safety Authority and the support of the EU Commission. In addition, 6 member states continue to maintain illegal marketing bans on a number of approved biotech events.

Regulations 1829/2003 and 1830/2003 are frequently difficult to understand and comply with and have had an adverse impact on trade. The Commission has been slow to provide guidance documents to help exporters interpret these new regulations. In particular, exporters have had difficulty determining if their product (s) are subject to the new labeling requirements. Finally, the EU has decided that products (such as beer, wine and cheese) that are produced with genetically modified "processing aids" are not subject to these regulations. This is inconsistent with the intent of the new regulations.

In accordance with DG Agriculture's guidance document on the coexistence of biotech and conventional crops, which recommended a regional approach to coexistence issues, a number of member states, including Denmark, Germany, and three regions in Austria, have drafted new coexistence laws. These laws have taken a maximalist approach, requiring extensive liability systems be put in place and mandating extremely low thresholds for adventitious presence. Once enacted, the European Commission may initiate infringement proceedings against a member state's coexistence law if it is judged to be incompatible with EU law. However, there is no time limit on how quickly the Commission must act.

Marketing Issues

The breakdown in the EU's approval process for products made from biotechnology has blocked most U.S. exports of corn and hinders trade in other products. Many food processors and exporters have either reformulated or sought out non-biotech sources in response to the implementation of mandatory traceability and labeling requirements in April 2004. Consumer ready products have been particularly hard hit. Most European retailers' own-store brands are non-GM, while they may consider carrying private supplier brands containing biotech ingredients. Since labeling hasn't been required for animal products such as meat and dairy, biotech feed ingredients have generally fared better. Reportedly, about 2/3 of the animal feed consumed in the EU is currently labeled as genetically modified. However, some consumer groups are pressuring retailers to carry meat and dairy products produced from non-biotech feed ingredients.

In a recent Eurobarometer poll on the environment, Europeans responded that the impact of chemicals (41 percent) and biotechnology (40 percent) were the two areas in which they most lacked information. Biotechnology continues to be more of a political than a scientific issue in Europe and the prospects for improvement remain dim.

Exports of Bt10 Corn

On March 22, 2004 Commission officials were advised that the company Syngenta had inadvertently marketed the biotech corn Bt10 in the United States from 2001-2004. Since Bt10 had not been authorized for marketing in the EU, the Commission introduced emergency inspection measures to identify the presence of Bt10 in exports of corn gluten feed and brewers grains to the EU. The inspection system went into effect on April 18 2005, and will remain in place for 6 months at which time a review will be conducted to determine whether it is still necessary. In 2003/04, the United States shipped about 3.4 million tons of corn gluten feed, a pelletized feed ingredient valued at about $340 million, to the European Union as a feed ingredient used in compound animal feed. To date, no shipments of corn gluten have tested positive for Bt10.

Capacity Building and Outreach

Post has participated in two major outreach activities over the last year that were funded by the Department of State. Working with the European Policy Center, the Embassy of the United States to Italy and the US Mission to the European Union organized a two-day Conference on "*The EU, the US and Modern Biotechnology*" on 1 and 2 October 2004 in Perugia, Italy. The conference focused on EU and US approaches to regulating biotech products, drawing a wide range of participants from government, universities, business and NGOs.

FAS Bucharest and the UN Environmental Program organized a similar conference in Bucharest, Romania that featured the Agricultural Minister Counselor from FAS Brussels and several European speakers. With area in herbicide tolerant soybeans now reaching 100,000 hectares and Romania slated for accession to the EU in 2007, this was an excellent opportunity to underscore the benefits of biotechnology.

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